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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,045	01/11/2005	Daniel Rachlin	336-1102US	6611
23429 7590 12/31/2007 GREGORY SMITH & ASSOCIATES 3900 NEWPARK MALL ROAD, 3RD FLOOR NEWARK, CA 94560			EXAMINER BOR, HELENE CATHERINE	
			ART UNIT 3768	PAPER NUMBER
			MAIL DATE 12/31/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/521,045

Applicant(s)

RACHLIN ET AL.

Examiner

Helene Bor

Art Unit

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is drawn to "an interface device" which is subcombination for use with a high frequency ultrasound imaging transducer but the claims are defining structure in relation to the transducer which is an unclaimed element of an intended combination. To avoid improperly claiming in the manner, the phrase "said distal end extending past a distal end of the transducer" could be "configured to extend past..." and "said reservoir maintains a fluid tight seal around the transducer" could be "configured to maintain..." Without positively claiming the combination including the transducer, it is not proper to recite "extending past" and "maintaining". Also the same issue is raise with the claim language of Claim 9 with reference to "the length of the device pas the transducer".
3. Claim 10, 14 & 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims 10, 14 & 18 fail to impose a structural limitation or requirement.

5. Claim 1-7, 9, 11-13, 15 & 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katsumata et al. (US Patent No. 5,078,149).

Claim 1: Katsumata teaches an interface device for use with an ultrasound imaging system having a scan head with at least one transducer (Abstract). While Katsumata does not specifically mention for use with a high frequency ultrasound imaging system, Katsumata does teach the use of the system to be adapted for various ultrasound probes (Col. 11, Line 17-23). It would have been obvious to one of ordinary skill in the art to modify the intervention of Katsumata for the use of high frequency ultrasound because of the easy handling and simple manufacture (Col. 3, Line 37-40). Katsumata teaches the interface device being removably attachable to the scan head (Col. 4, Line 21-26). Katsumata teaches an interface device comprising a reservoir with a proximal end and a distal end (Figure 4A, Elements 11 & 15). Katsumata teaches the proximal end being open (Figure 4A, Element 15). Katsumata teaches a reservoir shaped to allow the transducer to transverse across an intended scan path within said reservoir (Col. 11, Line 24-40). Katsumata teaches the distal end extending past a distal end of the transducer (Figure 5, Element 12 & 18) and including a scan window through which ultrasound energy is transmitted and received (Col. 4, Line 20-26). Katsumata teaches the reservoir maintaining a fluid tight seal around the transducer (Col. 9, Line 1-10) and a fluid coupling medium located within the reservoir (Figure 4A, Element 17).

Claim 2: Katsumata teaches the interface device being sterile (Col. 5, Line 47-53).

Claim 3: Katsumata teaches how to achieve low ultrasound attenuation (Col. 8, Line 9-15). The equation for Attenuation is: $1/2 \times \text{Frequency (MHz)} \times \text{path length (cm)}$. Attenuation is dependent on the frequency¹. So when Katsumata teaches a decrease in attenuation it is understood likewise a decrease in frequency as well. It would have been obvious to one of ordinary skill in the art to modify the teachings of Katsumata to design the ultrasound scan window with as little ultrasound attenuation [signal loss] as possible.

Claim 4: Katsumata teaches the scan window comprising a non-flowable hydrogel (Figure 5, Element 17 & 21).

Claim 5: Katsumata teaches the scan window comprises a non-flowable hydrogel and a porous support structure (Figure 8B, Elements 63 & 57 and Element 63).

Claim 6: Katsumata teaches the hydrogel comprising a crosslinked polymer with water content greater than or equal to 50% by weight (Col. 8, Line 9-15).

Claim 7: Katsumata teaches the hydrogel comprising polyethylene oxide (Col. 4, Line 10-12).

Claim 9: Katsumata teaches the length of the device past the transducer is adjustable to allow adjustment of the position of the transducer focus (Col. 11, Line 52-58). Katsumata explains that the device is capable of movement in relation to the ultrasonic probe and ultrasonic coupler.

¹ Helguera, Maria Dr. "An Introduction to Ultrasound". Rochester Institute of Technology Rochester. 13 December 2007 <<http://www.cis.rit.edu/research/ultrasound/ultraintro.htm>> 8 April 2007.

Claim 11: Katsumata teaches a device wherein the distal end of the device is curved to approximate the radius of the eye (Col. 4, Line 45-51).

Claim 12: Katsumata teaches a device wherein the reservoir comprises one or more separate pieces between which is disposed the hydrogel scan window (Figure 4A, Element 16 & 11).

Claim 13: Katsumata teaches a device incorporating delivery of fluid [gel] acoustic coupling material (Figure 8B, Element 63).

Claim 15: Katsumata teaches a device that incorporates access for surgical instruments (Figure 7). The device of Katsumata does not require an eyecup for operation and thus allows for access for surgical instruments as applicant stated that an eyecups is cumbersome and limits the use of ultrasound imaging during surgical procedures.

Claim 18: Katsumata teaches a device that is sterilized by ionizing radiation (Col. 5, Line 47-53).

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Katsumata (US Patent No. 5,078,149) as applied to Claim 4 above and further in view of Matthews'123 (US Patent No. 3,939,123).

Claim 8: Katsumata teaches an overview of hydrogel composition but does not elaborate regarding more specific compositions and types. However Matthews teaches hydrogel formed from polyisocyanate terminated poly(alkylene ether) polyols (Col. 2, Line 13-49). It would have been obvious to one of ordinary skill in the art at the time of the invention was made to combine the teachings of Katsumata and Matthews in order

to produce a hydrogel with high water absorberency (Col. 5, Line 1-6) because high water content reduces attenuation (Katsumata; Col. 8, Line 9-15).

7. Claim 10 & 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katsumata as applied to Claim 1 above and further in view of Puech (US Patent No. 6,837,855 B1).

Claim 10: Katsumata fails to teach the focus range of the device. However, Puech'855 teaches a device wherein the transducer focus is in the range of 2 to 6 mm past the distal the edge of the device (Col. 6, Line 38-48). It would have been obvious to one of ordinary skill in the art at the time of the invention was made to combine the teachings of Katsumata and Puech in order to for specific exploration of the anterior segment of the eye (Col. 6, Line 38).

Claim 14: Katsumata fails to teach wherein the ultrasound frequency is in the range of 50 to 100 MHz (Col. 4, Line 41-50 & Col. 6, Line 38-48). It would have been obvious to one of ordinary skill in the art at the time of the invention was made to combine the teachings of Katsumata and Puech in order to have better image resolution (Col. 2, Line 15-18).

8. Claim 16 & 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katsumata as applied to Claim 1 above and further in view of de Juan et al. (US Patent Application No. 2001/0029335 A1).

Claim 16: Katsumata fails to teach the surgical instrument. However, de Juan'335 teaches the device incorporating a surgical instrument (Figure 5A, Element 305a & 206, Figure 6A & 6B and Page 4, Paragraph 0042). It would have been obvious

to one of ordinary skill in the art at the time of the invention was made to combine the teachings of Katsumata and de Juan in order for a surgeon to scan the retina during the procedure to evaluate the effectiveness of the action taken (Page 4, Paragraph 0046).

Claim 17: Katsumata fails to teach the surgical instrument. However, de Juan teaches the device wherein the device incorporates a surgical instrument that allows use of the instrument in positional relationship to the scanned image (Page 1, Paragraph 0010). It would have been obvious to one of ordinary skill in the art at the time of the invention was made to combine the teachings of Katsumata and de Juan in order to better plan the surgical approach and provide high resolution images.

Response to Arguments

9. Applicant's arguments filed 10/01/2007 have been fully considered but they are not persuasive. Applicant asserted that the transducer of Katsumata would not allow for movement within the holder. The examiner respectfully disagrees. The structure of Katsumata is capable of movement of the transducer within the holder. Katsumata teaches the holder adaptable to fit mechanical scan probes as shown in Figure 11 A & B and further described in Col. 11, Line 17-19. The mechanical scanning probe moves the transducer within the holder wherein the holder is shaped to allow transducer movement. The Applicant asserts that Katsumata does not teach fluid tight seals. However, the examiner respectfully disagrees. Katsumata teaches an ultrasound coupler fixed to the probe (Col. 9, Line 10-14). The coupler is designed to contain the gel [fluid] within the holder (Col. 5, Line 19-31). Applicant asserts that Katsumata teaches away from Applicant's claimed configuration. However, Applicant did not

further elaborate as to how. The examiner respectfully disagrees with the assertion. Applicant argues that Katsumata does not teach allowable signal loss of 1 db/mm and does not describe the frequency dependence of the ultrasonic wave attenuation. The examiner respectfully disagrees. Katsumata teaches how to achieve low ultrasound attenuation (Col. 8, Line 9-15). The equation for Attenuation is: $1/2 \times \text{Frequency (MHz)} \times \text{path length (cm)}$. Attenuation is dependent on the frequency. So when Katsumata teaches a decrease in attenuation it is understood likewise a decrease in frequency as well. Applicant argued that the combination of Matthews and Katsumata. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., water content of 50%) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims stated "with water content *greater than* or equal to 50% by weight". Katsumata does teach using with water content greater than 50% by weight (Col. 8, Line 9-14). It is noted that no additional arguments than those addressed above are presented with respect to the combinations of Katsumata and Puech and Katsumata and de Juan.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helene Bor whose telephone number is 571-272-2947. The examiner can normally be reached on M-T 8:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 ERIC F. WINAKUR
PRIMARY EXAMINER